

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**Medicare Reimbursement of
End Stage Renal Disease Drugs**



**JUNE GIBBS BROWN
Inspector General**

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OEI-03-00-00020**

OFFICE OF INSPECTOR GENERAL

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EXECUTIVE SUMMARY

PURPOSE

This inspection compares Medicare payment amounts for end stage renal disease drugs (ESRD) with amounts paid by Medicaid and the Department of Veterans Affairs.

BACKGROUND

Generally, Medicare does not pay for most over-the-counter or outpatient prescription drugs. However, Medicare Part B does cover certain drugs furnished by independent dialysis facilities. These drugs must be medically necessary and be included in the list of “separately billable drugs” found in the *Renal Dialysis Facility Manual*, Section 318.1. Medicare’s total charges for ESRD drugs provided by independent dialysis facilities exceeded \$1.4 billion in 1998.

Prescription drugs furnished by independent dialysis facilities are reimbursed by Medicare fiscal intermediaries from the Medicare Part B fund. In general, a covered drug is reimbursed at 95 percent of the drugs’ average wholesale price (AWP). Medicare beneficiaries are responsible for a 20 percent copayment. State Medicaid agencies have the authority to develop their own reimbursement methodology for outpatient prescription drugs under the pharmacy benefit. Like Medicare, most Medicaid agencies use AWP as the basis for calculating their drug reimbursement amounts. Additionally, drug manufacturers are required by law to enter into rebate agreements with Medicaid in order to participate in the program. Unlike Medicare and Medicaid, the Department of Veterans Affairs (VA) purchases drugs for its healthcare system directly from manufacturers or wholesalers. There are several purchase options available to the VA, including the Federal Supply Schedule, Blanket Purchase Agreements, and VA national contracts.

We focused our inspection on just five drug codes, which accounted for \$379 million in total charges to Medicare in 1998. We compared Medicare’s fourth quarter 1999 reimbursement amounts for these drugs to Medicaid amounts and VA acquisition costs.

FINDINGS

Medicare allowed amounts would be nearly halved for five ESRD drugs if amounts were based on VA acquisition costs

Medicare allowed amounts during the fourth quarter of 1999 were greater than the VA acquisition costs for the five drugs reviewed. For two drugs, Medicare allowed amounts

were more than double the VA's contracted price. Medicare would save between 37 and 56 percent for each of the five drugs if its allowed amounts were equal to VA acquisition costs.

Medicare would save between 5 and 38 percent for five ESRD drugs if its allowed amounts were equal to Medicaid reimbursement including rebates

Medicare allowed amounts were greater than Medicaid amounts for each of the five reviewed drugs during the fourth quarter of 1999. Medicaid amounts include any rebates calculated for the drugs. Medicare allowed amounts exceeded Medicaid amounts by a only a small percentage for two of the drugs since Medicaid agencies did not receive rebates for these specific products. For two drugs, the Medicaid amount was approximately one-third less than the Medicare allowed amount.

While we were able to determine percentage differences between the Medicare allowed amounts and other agencies' costs for the reviewed drugs, we could not prepare a precise estimate of dollar savings. The only reimbursement information available to us represented the total amount billed to Medicare for ESRD drugs and not the total amount which was paid. However, if the percentage savings that we calculated for each drug were applied to Medicare's total charges (i.e., the amount billed), then Medicare could have saved up to \$42 million in 1998 if their allowed amounts equaled Medicaid amounts. Medicare could have saved up to \$162 million in 1998 if their allowed amounts equaled VA acquisition costs. Because total charges are often inflated, we recognize that the estimates provided are the most that Medicare could have possibly saved. However, even if the savings did not reach these maximum levels, the potential savings would still be substantial.

RECOMMENDATION

The Department of Veterans Affairs (VA) purchases drugs for its healthcare system directly from manufacturers or wholesalers. Conversely, Medicare and Medicaid reimburse doctors and suppliers for drugs which they administer or supply to beneficiaries. We recognize that the Health Care Financing Administration (HCFA), Medicaid, and the VA operate under different statutory constraints. Nevertheless, the fact remains that other government entities can get certain prescription drugs at drastically lower prices than Medicare.

Our current findings provide further support for recommendations made in earlier reports. We previously recommended, and HCFA concurred, that HCFA re-examine its Medicare drug reimbursement methodologies with the goal of reducing payments as appropriate. We outlined a number of options for implementing this recommendation, including: (1) greater discounting of published average wholesale prices, (2) basing payment on acquisition costs, (3) establishing manufacturers' rebates similar to those used in the Medicaid program, and (4) using competitive bidding.

We continue to support the need for lower drug prices for the Medicare program and its beneficiaries. We realize, however, that HCFA's power to lower drug prices through the use of its inherent reasonableness authority was recently limited by a provision of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999. Therefore, we recommend that HCFA press for legislative efforts which would (1) immediately lower the price of these five ESRD drugs, (2) use the Federal Supply Schedule (FSS) as a basis for developing Medicare allowed amounts, or (3) reform the current drug pricing methodology in another manner which would substantially lower unreasonable prescription drug prices.

Agency Comments

The HCFA concurred with our recommendation, noting that basing reimbursement on acquisition cost is probably the best way to ensure that Medicare pays fair prices for covered drugs. Additionally, HCFA gave a detailed account of their numerous attempts to lower unreasonable drug reimbursement amounts in the Medicare program. Currently, HCFA plans to utilize a number of more accurate drug prices developed by First Databank, publisher of a pricing compendium used by the pharmaceutical industry. HCFA requested that Medicare contractors use these prices when calculating their drug reimbursement amounts. The HCFA also commented that they are working to develop a comprehensive electronic file on the pricing of Medicare covered drugs, and are continuing a competitive bidding demonstration project for albuterol in Texas. In addition, HCFA is consulting with the Department of Justice and the Office of Inspector General on the feasibility of developing additional means to ensure that accurate drug pricing data is used in setting Medicare reimbursement rates. The full text of HCFA's comments is presented in Appendix D.

We commend HCFA's efforts to lower Medicare drug reimbursement rates. We fully support attempts to obtain more accurate prices for the Medicare program. We believe that HCFA's request that Medicare contractors use the more accurate prices supplied by First Databank is a significant first step towards reimbursing drugs in a more appropriate manner.

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INTRODUCTION

PURPOSE

This inspection compares Medicare payment amounts for end stage renal disease (ESRD) drugs with amounts paid by Medicaid and the Department of Veterans Affairs.

BACKGROUND

Medicare Coverage of ESRD Drugs

Generally, Medicare does not pay for most over-the-counter or outpatient prescription drugs. However, under specific circumstances, Medicare Part B will cover drugs used in association with organ transplantations, chemotherapy, durable medical equipment, infusion devices, and vaccinations. Additionally, Medicare Part B covers certain drugs furnished by independent dialysis facilities that are not included in the ESRD composite rate payment. These drugs must be medically necessary and be included in the list of “separately billable drugs” found in the *Renal Dialysis Facility Manual*, Section 318.1.

The ESRD facility composite rate payment includes almost all per treatment costs for an ESRD patient and is paid by fiscal intermediaries from the Part A fund. Separately billable ESRD drugs furnished by independent dialysis facilities are reimbursed by fiscal intermediaries from the Part B fund.

Medicare’s total charges for ESRD drugs provided by independent dialysis facilities exceeded \$1.4 billion in 1998. This figure represents the amount which was billed to Medicare.

Medicare Drug Reimbursement

The Health Care Financing Administration (HCFA), which administers the Medicare program, has required Medicare Part B carriers to calculate payment allowances for covered drugs. To ensure uniform pricing, Part B carriers are then required to furnish the allowed amounts for the drugs to the Part A intermediaries operating in their jurisdiction.

Medicare’s current reimbursement methodology for prescription drugs is defined by Section 4556 of the Balanced Budget Act of 1997. Carriers base their payment amount for a drug on its average wholesale price (AWP) as published in *Drug Topics Red Book* or similar pricing publications used by the pharmaceutical industry. If a drug is available only in brand form, reimbursement is calculated by taking 95 percent of the drug’s AWP. If a drug has both brand and generic sources available, reimbursement is based on 95 percent of the median AWP for generic sources. However, if a brand name product’s

AWP is lower than the median generic price, Medicare reimburses 95 percent of the lowest brand price. Medicare beneficiaries are responsible for a 20 percent copayment for covered drugs.

Section 4316 of the Balanced Budget Act of 1997 allows HCFA to diverge from the statutorily defined payment method if the method results in payment amounts which are not inherently reasonable. However, HCFA's ability to use its inherent reasonableness authority was recently limited by a provision of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999. In short, this provision requires that before HCFA can invoke this authority, a study must be performed by the Comptroller General to determine the potential effects of utilizing inherent reasonableness measures. Furthermore, the criteria used in identifying excessive payments must be re-evaluated, and its validity and reliability ensured.

Medicaid Drug Reimbursement

Each State Medicaid agency has the authority to develop its own reimbursement methodology, subject to upper limits set by HCFA. Like Medicare, most Medicaid agencies use AWP as the basis for calculating their reimbursement amounts for outpatient drugs. However, Medicaid agencies generally use a more deeply discounted AWP than does Medicare.

Additionally, drug manufacturers are required by Federal law to enter into rebate agreements with Medicaid in order to be eligible for Medicaid reimbursement of their products. While most drugs are subject to these requirements, certain products, such as vaccines, which meet specific statutory guidelines are exempt from rebates.

In 1999, the quarterly rebate for brand-name drugs was based on either 15.1 percent of the average manufacturer price (AMP) or the difference between the AMP and the best price, whichever was greater. The AMP is the average price paid by wholesalers for products distributed for retail trade. Best price is the lowest price paid by any purchaser with the exception of Federal agencies and State pharmaceutical assistance programs. The rebate amount for generic drugs was 11 percent of AMP.

Department of Veterans Affairs Drug Reimbursement

Unlike Medicare and Medicaid, the Department of Veterans Affairs (VA) purchases drugs for its healthcare system directly from manufacturers or wholesalers. There are several purchase options available to the VA, including the Federal Supply Schedule, Blanket Purchase Agreements, and VA national contracts.

The Federal Supply Schedule provides agencies like the VA with a simple process for purchasing commonly used products in various quantities while still obtaining the discounts associated with volume buying. Using competitive procedures, contracts are awarded to companies to provide services and supplies over a given period of time. Although the General Services Administration awards most Federal Supply Schedule

contracts, the VA awards contracts for certain medical items. Agencies are not required to use the Federal Supply Schedule, however, and are sometimes able to negotiate prices lower than the Federal Supply Schedule price.

Related Work by the Office of Inspector General

The Office of Inspector General (OIG) has previously studied a number of issues related to Medicare prescription drug reimbursement. Brief summaries of selected studies are presented in Appendix A.

METHODOLOGY

Medicare Charges for Prescription Drugs

To determine total Medicare charges for ESRD drugs, we compiled a list of revenue center codes representing drugs covered by Medicare in 1998. Revenue center codes are codes which facilities use to define the product or service provided. We selected 1998 because it was the most recent year with complete data in HCFA's National Claims History file. We then determined the Medicare total charges and services billed by independent dialysis facilities for each of these revenue center codes. We aggregated the charges for the individual revenue center codes in order to determine total Medicare charges for ESRD drugs provided by independent dialysis facilities in 1998.

Medicare Part B's total charges for ESRD drugs furnished by independent dialysis facilities totaled more than \$1.4 billion in 1998. Approximately \$1 billion of the total charges were for epoetin alfa (revenue center codes 0634 and 0635). We decided to exclude epoetin alfa from our review because its pricing had been previously reviewed by our Office of Audit Services. Nearly all of remaining charges were made using revenue center code 0636, defined as "drugs requiring specific identification--detailed coding." Drugs billed using this revenue center code are specifically identified using the HCFA Common Procedure Coding System (HCPCS). A HCPCS code defines the type of drug billed, and in most cases, a dosage amount. Using the National Claims History file, we determined that in 1998, five HCPCS codes accounted for \$379 million (90 percent) of the \$424 million in total charges for revenue center code 0636. A list of the reviewed HCPCS codes along with their definitions is presented in Appendix B.

Medicare Pricing for ESRD Drugs

Because Medicare does not have uniform national allowed amounts for prescription drugs, we collected payment information from individual contractors. We obtained Medicare drug payment amounts for the five contractors with the highest charges for ESRD drugs in 1998: Trailblazer Health Enterprises of Texas, Blue Cross and Blue Shield of Georgia, Blue Cross of California, Blue Cross and Blue Shield of Florida, and Empire Blue Cross

and Blue Shield of New York. To determine a single Medicare allowed amount, we calculated median prices for each HCPCS code based on the information provided.

Matching HCPCS Codes to National Drug Codes

Unlike Medicare, Medicaid and the VA use national drug codes (NDCs) rather than HCPCS codes to identify drugs products. Each drug manufactured or distributed in the United States has a unique NDC. The NDCs identify the manufacturer of the drug, the product dosage form, and the package size. From the NDCs, the drugs can be identified as either brand or generic.

Because of these coding differences, we used *Drug Topics Red Book* to identify the specific NDCs that would match the HCPCS code definition for each of the five drugs in our review. For each drug, we selected the NDCs which met the exact dosage and administration method delineated in the HCPCS code description. When this was not possible, we chose NDCs with dosage amounts for which a conversion factor to the HCPCS definition could be readily determined. Four of the five HCPCS codes had only one NDC which met our matching criteria. One HCPCS code had three matching NDCs.

Medicaid Pricing of ESRD Drugs

For our comparison, we used Medicaid reimbursement for prescription drugs under each state's pharmacy benefit. We gathered this information from the publication *Pharmaceutical Benefits under State Medical Assistance Programs, December 1998* to determine each Medicaid agency's reimbursement methodology for outpatient prescription drugs. Forty-five of the 51 agencies utilized pricing methodologies that were based on AWP. The remaining six agencies priced their drugs using more complicated methods and were eliminated from our review. We arrayed the remaining 45 Medicaid agencies by the amount that their pricing methodology discounted AWP. We then calculated the mean (9.87 percent), median (10 percent), and modal (10 percent) AWP discounts. A complete list of each Medicaid agency's pricing methodology is presented in Appendix C.

We used *Drug Topics Red Book October 1999 Update* to determine the fourth quarter 1999 AWP of the selected codes. We then determined base Medicaid prices for the five drugs by reducing the AWP by the median discount of 10 percent, recognizing that some States may pay slightly more and others slightly less. If the NDC dosage of the drug did not exactly match the HCPCS dosage, we multiplied the base Medicaid price by a conversion factor so that the Medicaid and Medicare prices would be for equal amounts of the drug.

We accessed the Medicaid Drug Rebate Initiative system to ascertain the Medicaid rebate amounts for each of the drugs. We used the most recent rebate amounts available for each NDC code, which in most cases was the third quarter of 1999. For the one drug which had multiple NDC matches, we chose the most conservative rebate amount. Additionally, Medicaid did not receive rebates for two of the drugs. For three NDCs, the

listed rebate was a for a dosage amount which was not equal to the HCPCS dosage amount. In these cases, a conversion factor was used to calculate a rebate amount for the HCPCS dosage. For each drug, we calculated a new Medicaid price by subtracting any rebate amounts from the base Medicaid price.

VA Pricing of ESRD Drugs

To determine the VA's fourth quarter 1999 acquisition costs for the drugs in our review, we obtained a file from the VA containing their contracted acquisition costs. We looked up the corresponding contract price for each of the drugs by NDC code. For the drug which had multiple NDC matches, we took the highest VA price for the drug. We used the Federal Supply Schedule price for comparison purposes.

If the NDC dosage of the drug did not exactly match the HCPCS dosage, we multiplied the contracted price by a conversion factor so that the VA and Medicare prices would be for equal amounts of the drug.

Calculating Potential Medicare Savings

To calculate potential Medicare savings, we compared the Medicare, Medicaid, and VA prices. For each drug, we determined the percentage difference between the Medicare payment amount and the other agencies' payment amounts. This percentage indicated how much Medicare could have saved on each of the drugs if their payment amounts equaled amounts paid by Medicaid and the VA.

FINDINGS

Medicare allowed amounts would be nearly halved for five ESRD drugs if amounts were based on VA acquisition costs

Medicare allowed amounts during the fourth quarter of 1999 were greater than VA acquisition costs for the five drugs reviewed. For two drugs, levocarnitine and the hepatitis B vaccine, Medicare allowed amounts were more than double the VA's contracted price. Medicare would save between 37 and 56 percent for each of the five drugs if its allowed amounts were equal to VA acquisition costs. Table 1 provides the reviewed drugs, their comparative costs to Medicare and the VA, and potential Medicare savings.

Table 1: Medicare and VA Drug Payment Amounts

HCPCS Code	Generic Drug Name	Medicare Allowed Amount	VA Acquisition Cost	Potential Medicare Savings
J0635	Calcitriol	\$12.83	\$8.10	36.9%
J1760	Iron Dextran	\$35.82	\$19.41	45.8%
J1955	Levocarnitine	\$34.20	\$15.08	55.9%
J3364	Urokinase	\$56.61	\$31.70	44.0%
90747	Hepatitis B Vaccine	\$172.23	\$84.36	51.0%

Medicare would save between 5 and 38 percent for five ESRD drugs if its allowed amounts were equal to Medicaid reimbursement including rebates

Medicare allowed amounts were greater than Medicaid amounts for each of the five reviewed drugs during the fourth quarter of 1999. Medicaid amounts include any rebates that were calculated for the drugs. Medicare allowed amounts exceeded Medicaid amounts by a only a small percentage for two of the drugs, calcitriol and the hepatitis B

vaccine, because Medicaid agencies did not receive rebates for these specific products. For two drugs, levocarnitine and urokinase, the Medicaid amount was approximately one-third less than the Medicare allowed amount. Table 2 provides the reviewed drugs, their comparative costs to Medicare and Medicaid, and potential Medicare savings.

Table 2: Medicare and Medicaid Payment Amounts

HCPCS Code	Generic Drug Name	Medicare Allowed Amount	Medicaid Amounts with Rebate	Potential Medicare Savings
J0635	Calcitriol	\$12.83	\$12.15	5.3%
J1760	Iron Dextran	\$35.82	\$31.77	11.3%
J1955	Levocarnitine	\$34.20	\$23.85	30.3%
J3364	Urokinase	\$56.61	\$35.23	37.8%
90747	Hepatitis B Vaccine	\$172.23	\$163.17	5.3%

While we were able to determine percentage differences between the Medicare allowed amounts and other agencies' costs for the reviewed drugs, we could not prepare a precise estimate of dollar savings. The only reimbursement information available to us represented the total amount billed to Medicare for ESRD drugs and not the total amount which was paid. However, if the percentage savings that we calculated for each drug were applied to Medicare's total charges (i.e., the amount billed), then Medicare could have saved up to \$42 million in 1998 if their allowed amounts equaled Medicaid amounts. Medicare could have saved up to \$162 million in 1998 if their allowed amounts equaled VA acquisition costs. Because total charges are often inflated, we recognize that the estimates provided are the most that Medicare could have possibly saved. However, even if the savings did not reach these maximum levels, the potential savings would still be substantial.

RECOMMENDATION

The Department of Veterans Affairs (VA) purchases drugs for its healthcare system directly from manufacturers or wholesalers. Conversely, Medicare and Medicaid reimburse doctors and suppliers for drugs which they administer or supply to beneficiaries. We recognize that the Health Care Financing Administration (HCFA), Medicaid, and the VA operate under different statutory constraints. Nevertheless, the fact remains that other government entities can get certain prescription drugs at drastically lower prices than Medicare.

Our current findings provide further support for recommendations made in earlier reports. We previously recommended, and HCFA concurred, that HCFA re-examine its Medicare drug reimbursement methodologies with the goal of reducing payments as appropriate. We outlined a number of options for implementing this recommendation, including: (1) greater discounting of published average wholesale prices, (2) basing payment on acquisition costs, (3) establishing manufacturers' rebates similar to those used in the Medicaid program, and (4) using competitive bidding.

We continue to support the need for lower drug prices for the Medicare program and its beneficiaries. We realize, however, that HCFA's power to lower drug prices through the use of its inherent reasonableness authority was recently limited by a provision of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999. Therefore, we recommend that HCFA press for legislative efforts which would (1) immediately lower the price of these five ESRD drugs, (2) use the Federal Supply Schedule (FSS) as a basis for developing Medicare allowed amounts, or (3) reform the current drug pricing methodology in another manner which would substantially lower unreasonable prescription drug prices.

Agency Comments

The HCFA concurred with our recommendation, noting that basing reimbursement on acquisition cost is probably the best way to ensure that Medicare pays fair prices for covered drugs. Additionally, HCFA gave a detailed account of their numerous attempts to lower unreasonable drug reimbursement amounts in the Medicare program. Currently, HCFA plans to utilize a number of more accurate drug prices developed by First Databank, publisher of a pricing compendium used by the pharmaceutical industry. HCFA requested that Medicare contractors use these prices when calculating their drug reimbursement amounts. The HCFA also commented that they are working to develop a comprehensive electronic file on the pricing of Medicare covered drugs, and are continuing a competitive bidding demonstration project for albuterol in Texas. In addition, HCFA is consulting with the Department of Justice and the Office of Inspector General on the feasibility of developing additional means to ensure that accurate drug pricing data is used in setting Medicare reimbursement rates. The full text of HCFA's comments is presented in Appendix D.

OIG Response

We commend HCFA's efforts to lower Medicare drug reimbursement rates. We fully support attempts to obtain more accurate prices for the Medicare program. We believe that HCFA's request that Medicare contractors use the more accurate prices supplied by First Databank is a significant first step towards reimbursing drugs in a more appropriate manner.

Previous OIG Reports on Medicare Drug Reimbursement

Comparing Drug Reimbursement: Medicare and the Department of Veterans Affairs (OEI-03-97-00293), November 1998. We found that Medicare and its beneficiaries would save \$1 billion in 1998 if the allowed amounts for 34 drugs were equal to prices obtained by the VA. Furthermore, Medicare allowed between 15 and 1600 percent more than the VA for the 34 drugs reviewed.

Are Medicare Allowances for Albuterol Sulfate Reasonable? (OEI-03-97-00292), August 1998. We found that Medicare would allow between 56 to 550 percent more than the VA would pay for generic versions of albuterol sulfate in 1998, and 20 percent more than the average Medicaid payment for albuterol sulfate in 1997. Additionally, Medicare allowed 333 percent more than available acquisition costs for the drug in 1998. Customers of mail-order pharmacies would pay up to 30 percent less than Medicare for albuterol sulfate in 1998.

The Impact of High-Priced Generic Drugs on Medicare and Medicaid (OEI-03-97-00510), July 1998. We found that Medicare and its beneficiaries could have saved between \$5 million and \$12 million for four drugs if reimbursement had not been based on higher-priced generic versions. Florida's Medicaid program would have saved half a million dollars for eight drugs in 1996 if higher-priced generic drugs had been reimbursed at brand prices.

Excessive Medicare Payments for Prescription Drugs (OEI-03-97-00290), December 1997. We found that Medicare allowances for 22 drugs exceeded actual wholesale prices by \$447 million in 1996. For more than one-third of the 22 drugs reviewed, Medicare allowed amounts were more than double the actual wholesale prices available to physicians and suppliers. Furthermore, we found that there was no consistency among Medicare carriers in establishing and updating drug reimbursement amounts.

Appropriateness of Medicare Prescription Drug Allowances (OEI-03-96-00420), May 1996. We found that under a drug rebate program similar to Medicaid's, Medicare would have saved \$122 million for 17 prescription drugs in 1994. Medicare could have saved an additional \$144 million in 1994 had the program employed a discounted AWP drug reimbursement formula. We also found that the lack of an NDC-based billing system would prevent HCFA from taking advantage of rebates and other discounted reimbursement formulas.

A Comparison of Albuterol Sulfate Prices (OEI-03-94-00392), June 1996. We found that many of the pharmacies surveyed charged customers less than the Medicare allowed amount for generic albuterol sulfate. The five buying groups surveyed had negotiated prices between 56 and 70 percent lower than Medicare's reimbursement amount for the drug.

Suppliers' Acquisition Costs for Albuterol Sulfate (OEI-03-94-00393), June 1996. We found that Medicare's allowances for albuterol sulfate substantially exceeded suppliers' acquisition costs for the drug, and that the program could have saved \$94 million during the 14-month review period if Medicare reimbursement amounts had been based on average supplier invoice costs.

Medicare Payments for Nebulizer Drugs (OEI-03-94-00390), February 1996. We found that Medicare and its beneficiaries paid about \$37 million more for three nebulizer drugs in 17 states than Medicaid would have paid for equivalent drugs. In addition, we found that the potential savings were not limited to the three nebulizer drugs and 17 states which were reviewed.

Description of HCPCS Codes

HCPCS Code	Generic Name	Method of Administration	Dosage Amount
J0635	Calcitriol	Injection	1 mcg
J1760	Iron Dextran	Injection	2 cc
J1955	Levocarnitine	Injection	1 g
J3364	Urokinase	Injection	5000 iu
90747	Hepatitis B Vaccine	Injection	40 mcg ¹

¹The dosage amount for HCPCS code 90747 is defined as “dialysis or immuno-suppressed patient dosage,” which according to the *Physician’s Desk Reference*, is equal to 40 mcg.

State Medicaid Outpatient Drug Pricing Methodologies

State	Reimbursement Basis
Alabama	WAC plus 9.2%
Alaska	AWP minus 5%
Arizona	AWP minus 10%
Arkansas	AWP minus 10.5%
California	AWP minus 5%
Colorado	AWP minus 10% or WAC plus 18%
Connecticut	AWP minus 12%
Delaware	AWP minus 12.9%
District of Columbia	AWP minus 10%
Florida	WAC plus 7%
Georgia	AWP minus 10%
Hawaii	AWP minus 10.5%
Idaho	AWP
Illinois	AWP minus 10% for single-source drugs, AWP minus 12% for multi-source drugs
Indiana	AWP minus 10%
Iowa	AWP minus 10%
Kansas	AWP minus 10%
Kentucky	AWP minus 10%
Louisiana	AWP minus 10.5%
Maine	AWP minus 10%
Maryland	WAC plus 10%
Massachusetts	WAC plus 10%
Michigan	AWP minus 13.5% or AWP minus 15.1%
Minnesota	AWP minus 9%
Mississippi	AWP minus 10%
Missouri	AWP minus 10.43%

APPENDIX C

State	Reimbursement Basis
Montana	AWP minus 10%
Nebraska	AWP minus 8.71%
Nevada	AWP minus 10%
New Hampshire	AWP minus 12%
New Jersey	AWP minus 10%
New Mexico	AWP minus 12.5%
New York	AWP minus 10%
North Carolina	AWP minus 10%
North Dakota	AWP minus 10%
Ohio	AWP minus 11%
Oklahoma	AWP minus 10.5%
Oregon	AWP minus 11%
Pennsylvania	AWP minus 10%
Rhode Island	WAC plus 5%
South Carolina	AWP minus 10%
South Dakota	AWP minus 10.5%
Tennessee	Individual managed-care and pharmacy benefit management organizations determine price
Texas	AWP minus 10.49% or WAC plus 12%
Utah	AWP minus 12%
Vermont	AWP minus 10%
Virginia	AWP minus 9%
Washington	AWP minus 11%
West Virginia	AWP minus 12%
Wisconsin	AWP minus 10%
Wyoming	AWP minus 4%

WAC=wholesalers acquisition cost; AWP=average wholesale price

Source: *Pharmaceutical Benefits Under State Medical Assistance Programs, December 1998*

Health Care Financing Administration Comments

In this appendix, we present, in full, comments from the Health Care Financing Administration.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

RECEIVED

JUN 13 2000 JUN 15 AM 10:43

TO: June Gibbs Brown
Inspector General

OFFICE OF INSPECTOR
GENERAL

FROM: Nancy-Ann Min DeParle
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Reports: "Medicare Reimbursement of End Stage Renal Disease Drugs," (OEI-03-00-00020) and "Medicare Reimbursement of Albuterol," (OEI-03-00-00311)

Thank you for your recent reports about the Administration's efforts to obtain fair prices for the limited number of drugs that Medicare currently covers and for your efforts to assist us in addressing the need to ensure that both Medicare and Medicaid pay appropriately for prescription drugs.

We have closely monitored the investigations of drug pricing conducted by the Department of Justice, the HHS Inspector General, and the State Medicaid Fraud Control Units (MFCUs). The reports echo our own concerns about the significant discrepancies between the prices that Medicare must pay by law and the significantly lower prices at which physicians may obtain certain drugs. I appreciate the opportunity to explain what we have done and the challenges we face in ensuring that Medicare pays fair prices.

The Health Care Financing Administration (HCFA) has been actively working to address this issue, both legislatively and through administrative actions, for many years. In 1991, the agency issued regulations to pay for these drugs based on the lower of the estimated acquisition cost or the average wholesale price. To implement this policy, HCFA developed a survey to get the necessary information from physicians. However, because of the wide range of drugs used in different amounts at different frequencies by different types of physicians in different geographic areas of the country, we would have had to survey virtually all physicians in order to get a statistically valid estimate of acquisition costs. Because that would have been burdensome and unfeasible, the Administration therefore determined that it would rely instead on the average wholesale price.

Because the estimated acquisition cost approach had proved unworkable, in 1997, the President proposed legislation to pay physicians their actual acquisition costs. Physicians would tell Medicare what they pay for drugs and be reimbursed that amount, rather than the Administration developing an estimate of acquisition costs and basing payment on the estimate. Unfortunately, Congress did not adopt the Administration's proposal. Instead, the Balanced Budget Act reduced Medicare payment for covered drugs from 100 percent to 95 percent of average wholesale price. This recaptures only a fraction of the excessive Medicare payment amounts because, until recently, available average wholesale price data did not correlate to actual wholesale prices for certain Medicare-covered drugs.

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In 1998, the President again proposed paying physicians their actual acquisition cost to “ensure that doctors are reimbursed no more, and no less, than the price they themselves pay for the medicines they give Medicare patients.” However, no Congressional action was taken.

Because Congress failed to act on the Administration’s 1997 and 1998 proposals, in 1999 and again this year, the President proposed a different legislative approach to achieve a similar result -- paying 83 percent of the average wholesale price instead of the 95 percent allowed by the Balanced Budget Act. We estimate that this would substantially reduce the pricing discrepancy, as well as any administrative burden associated with surveying vast numbers of physicians to estimate acquisition costs. The HCFA actuaries project that this legislative proposal would save Medicare \$2.9 billion over 10 years.

On May 31, 2000, we announced that we are now moving administratively to take advantage of the newly available, more accurate data on average wholesale prices developed for Medicaid as a result of Department of Justice investigations. These data are from catalogs of drug wholesalers, which the Department of Justice says account for a significant portion of the wholesale market. The Department of Justice and MFCUs have compiled data for about 400 national drug codes, representing about 50 different chemical compounds. The Department of Justice provided this information to First Data Bank, a company specializing in the compilation of drug pricing data (formerly known as the “Blue Book”) that is used to determine prices paid by State Medicaid programs. These drugs represent about one-third of Medicare spending for drugs.

To obtain the benefits of this new information in Medicare right away, we will provide to Medicare carriers the average of the wholesale catalog prices, as has been calculated by First Data Bank for Medicaid. In June, we will send this information to Medicare carriers so they can use it when they determine average wholesale prices for their next quarterly update of Medicare drug allowances, which will become effective on October 1, 2000. According to the General Counsel at the Department of Health and Human Services, this is the most immediate action we can take without going through the formal rule-making process.

We also are consulting with the Department of Justice and your office on the feasibility of developing additional means to ensure that accurate drug pricing data is used in setting Medicare rates. To monitor carrier activities, we are requiring carriers to send to HCFA, by September 15, 2000, a written explanation of the data sources used for determining payment allowances for these drugs. In addition, we have met with the company that publishes the “Red Book,” which is the source of average wholesale price data that most carriers have used to date, to discuss recent developments and the need for accurate data. Furthermore, we are considering whether to change our current legislative proposal for paying 83 percent of average wholesale prices to instead propose paying physicians their actual acquisition costs.

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Based on our recent discussions with the Department of Justice and your office, we believe that the Administration's original approach -- to base Medicare's payment for drugs on the physician's actual acquisition costs -- is probably the most effective means to ensure that Medicare is paying fairly. As part of this effort, we plan to work with physician groups to review the physician's ability to provide acquisition cost data, and to review payment rates for chemotherapy administration to ensure that they are adequate as we reduce payments for the drugs themselves to the prices that physicians pay.

In addition to the proposed legislation and administrative activity discussed above, we are taking several other steps to try to address Medicare drug pricing inequities.

- We are developing an electronic file of prices for Medicare covered drugs, as recommended in your December 1997 report. A contractor has been working on numerous technical issues, including the components necessary for appropriate drug pricing (e.g., route of administration, drug strength concentrations, available package size and most commonly used dosage ranges). We are hopeful that a report on this first phase of the project will be available by this summer.

A report on a second phase of work on issues relating to mapping between codes Medicare currently uses (the HCFA Common Procedure Coding System) and national drug codes, compatibility with the Health Insurance Portability and Accountability Act administrative simplification standards that are being developed, generic and brand name mapping, new drug entries, drug deletions, and updates, is expected by the end of the year. We believe this work will help us ensure that all carriers across the country have access to the most accurate average wholesale price data and will reimburse a uniform allowed amount for each drug code.

- We are using market forces and competition to set fairer prices for one drug -- Albuterol sulfate -- as part of a competitive bidding demonstration for durable medical equipment supplies in Texas. A similar demonstration in Florida, while not including drugs, is saving an average of 17 percent for beneficiaries and Medicare through the bidding process. We hope to be able to use the results from these demonstrations more generally in the Medicare program.
- Finally, we are awaiting a final General Accounting Office report on using the "inherent reasonableness" authority contained in the Balanced Budget Act of 1997. In September 1998, we proposed reducing excessive charges on several items, including Albuterol sulfate. Our contractors who process durable medical equipment claims surveyed retailers in 16 states and found that Medicare was paying substantially more than other payers.

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Congress, however, in the Balanced Budget Refinement Act of 1999, mandated that we not take action to finalize the proposed rule until a GAO study of our use of the inherent reasonableness authority is published. We just received the draft final report from the GAO and look forward to its final report so we can move forward to reduce these payments to reasonable levels.

We have also taken actions to help State Medicaid programs obtain fair prices for drugs.

- We have proposed sharing average manufacturer price data with States so they can accurately set Medicaid reimbursement rates. Current law requires drug manufacturers to report average manufacturer price data to HHS.
- We have proposed applying the consumer price index-urban (CPI-U) adjustment to generic drugs. Brand name drug manufacturers must pay an additional dollar-for-dollar rebate to Medicaid if they increase prices in excess of CPI-U. But, it is now clear that generic drug prices also sometimes increase faster than inflation.
- We plan to work with all State Medicaid programs regarding First Data Bank's announcement that it will revise the way it collects and reports average wholesale price data to them, based on information in wholesaler catalogs. This should create immediate benefits for all State Medicaid programs.

Finally, as you may know, the President has proposed a voluntary, comprehensive Medicare outpatient drug benefit available to all Medicare beneficiaries. A critical element of this proposal is the use of private pharmacy benefit managers who will negotiate prices with pharmaceutical companies, as they do now for most private insurance plans. This will help keep the benefit affordable without any statutory price setting, and avoid the types of concerns addressed in this response.

Thank you again for your time and effort on these important issues.

Attachment

ATTACHMENT

Comments of the Health Care Financing Administration on the
Office of Inspector General Reports: "Medicare Reimbursement of End State Renal Disease
Drugs," (OEI-03-00-00020) and "Medicare Reimbursement of Albuterol," (OEI-03-00-00311)

OIG Recommended Options

HCFA should examine its Medicare drug reimbursement methodologies with the goal of reducing payments as appropriate. Options include (1) greater discounting of published average wholesale prices, (2) basing payment on acquisition costs, (3) establishing manufacturers' rebates similar to those used in the Medicaid program, and (4) using competitive bidding.

HCFA Response

HCFA concurs with this recommendation and believes that our administrative action is an important step in assuring that Medicare pays fair and accurate prices for currently covered drugs. In addition, we also believe that the Administration's original approach -- to base Medicare's payment for drugs on the physician's actual acquisition costs -- is probably the most effective mean to ensure that Medicare is paying fairly. As part of this effort, we plan to work with the physician groups to review physician's ability to provide acquisition cost data, and to review payment rates for chemotherapy administration to ensure that they are adequate as we reduce payments for the drugs to the prices that physicians pay.